UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/848,967 | 05/04/2001 | Emanuel Calenoff | 21417/92378 | 6936 |

23644 7590 05/17/2004

BARNES & THORNBURG
P.O. BOX 2786
CHICAGO, IL 60690-2786

| EXAMINER | |
|---|---|
| CHEU, CHANGHWA J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1641 | |

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/848,967 | CALENOFF ET AL. | |
| | Examiner | Art Unit | |
| | Jacob Cheu | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *2//18/2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-3,17-19,21 and 22* is/are pending in the application.

4a) Of the above claim(s) *4-16 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,17-19,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's amendment filed on 2/18/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-3, 17-19 and 21-22 are pending.
2. Claims 4-6, 20 is withdrawn from further consideration.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 17, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Regenmortel (ASM News 1998 64: 332-338).

Regenmortel teaches developing synthetic peptides for vaccines by algorithms predictions. Regemortel teaches using mimotopes molecules which are small peptides, e.g. less than 100 amino acid, showing no sequence similarity with the viral proteins yet the molecules mimic in a immunofunctional sense. (page 334, right column, third paragraph) Regemortel discloses that in order to qualify as an mimotope, the peptides should not only bind to the vial antibodies but it should also be able to elicit antibodies that recognize the original antigen it is supposed to mimic. (see supra) Particularly, in Figure 4, the sample details every element of the recited claim 1-3, 17 and 21.

First, take HbsAg sequence 120-132 as an example.

HbsAg sequence 120-132 is a target protein.

HCV sequence 20-32 is a "comparative protein" meaning non-target protein having less than 50 % homology.

Mimotope 13 is the selected immunogenic peptide of the target protein because

(a) it is a 10 amino acid peptides

(b) derived from the target protein HbsAg sequence 120-132

(c) having a net hydrophilicity nature on the cell surface

(d) having less than 50 % than the non target comparative protein HCV sequence 20-32

(e) showing no more than 3 contiguous amino acids compared to comparative protein

(f) having an antigenic response mimic the target protein.

Other similar example can also be shown if use HCV 35-47 as the target protein, and mimotope 17 or mimotope 14 as comparative protein. The immunogenic peptide mimotope P715c will also fit the criteria as discussed above. Accordingly, Regenmortel's reference anticipated the current invention.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Regenmortel in view of Hasegawa et al. (US 4606857).

Regemortel teach using recombinatnt technique, e.g. pahge library, to synthesize peptides capable of producing immunogenicity to combat viral infection. (page 334-336) However Regemortel does not explicitly teach coupling the selected peptides with an adjuvant molecule to enhance immunogenicity of the peptide. Hasegawa et al. teach coupling a muramyl molecule to a peptide to enhance immunogenicity reaction. (See formula I, and col. 1, line 32-42) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Regemortel with the adjuvant molecule as taught by Hasegawa et al. to increase the efficacy of immunogenicity sicne it is well-known and common practice in the art to couple adjuvant molecule with the peptides for enhancement of immunogenicity.

4. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Regemortel in view of Tu et al. (US 5674483).

Regemortel reference has been discussed but is silent in teaching prescribing the peptide as a desensitizing agent for therapy purposes. Tu et al. teach a method of administering IL-2 in an effective amount to desensitize airway hyperactivity and subsequently prescribing IL-2 increasingly to induce immune tolerance to the specific respiratory antigens. (Col. 2, line 15-45) Tu et al. reveal that this method provides the advantages of less side effects and less toxicity. (Col. 2, line 1-10) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the peptides of Regemortel with the desensitizing method as taught by Tu et al. in order to reduce the immune tolerance, decrease side effects and toxicity, and maximize the expected results.

## Response to Applicant's Arguments

5. The rejections of claims 1-3, 17 under 35 USC 102(b) as anticipated in view of Barry et al. is withdrawn.

6. ~~The~~ The rejections of claims 1-3, 17, 21 under 35 USC 102(b) as anticipated in view of are maintained.

## With respect to the reference of Regemortel

7. Applicant's arguments focus on the teachings of Regemortel do not anticipate the instant invention, particularly Regemortel's mimotope lacks every feature as recited in claim 1. Applicant also points out that the mimotopes in the cited prior art "show no sequence similarity with the viral protein." The arguments have been considered but are not persuasive. The 102 (b)

rejection set forth in this Office Action is clearly established the statutory anticipation by the Regemortel reference. (See above) Furthermore, examiner would again stresses this issue that the current elected group is a PRODUCT claim. MPEP §2112 states "[Where] the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established." In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Applicant has shown that the so-called comparative proteins are *any* proteins less than 50% homology to the target proteins. This limitation can be any proteins has no homology at all to the target proteins, i.e. HbsAg 120-132 vs. HCV 20-32 as illustrated in the above example. As detailing in the above example, Regenmortel teaches every element in the current invention. Accordingly, applicant fails to show any novelty recited in the claims under 35 USC §102(b).

***Conclusion***

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641

May 5, 2004

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
05/12/04